F. FDA's Role in Switches

- Under what circumstances should FDA actively propose OTC marketing for a drug in the absence of support from the drug sponsor?
- Should FDA be more active in initiating switches of prescription products to OTC use?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs (the Commissioner) is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner or her designee. The presiding officer will be accompanied by a panel of Public Health Service employees with relevant expertise.

Persons who wish to participate in the part 15 hearing must file a written notice of participation with the Dockets Management Branch (address above) prior to June 2, 2000. To ensure timely handling, any outer envelope should be clearly marked with the Docket No. 00N–1256 and the statement ''FDA Regulation of OTC Drug Products Hearing.'' Groups should submit two copies. The notice of participation should contain the person's name; address; telephone number; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; brief summary of the presentation; and approximate amount of time requested for the presentation. The agency requests that interested persons and groups having similar interests consolidate their comments and present them through a single representative. FDA will allocate the time available for the hearing among the persons who file notices of participation as described above. If time permits, FDA may allow interested persons attending the hearing who did not submit a written notice of participation in advance to make an oral presentation at the conclusion of the hearing.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by telephone of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. The hearing schedule will be available at the hearing. After the hearing, the hearing schedule will be placed on file in the Dockets Management Branch under Docket No. 00N–1256.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). The transcript of the hearing will be available on the Internet at http://www.fda.gov/ohrms/dockets and orders for copies of the transcript can be placed at the meeting or through the Freedom of Information Staff (HFI–35), 5600 Fishers Lane, Rockville, MD 20857.

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the contact person listed above.

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

IV. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written notices of participation and comments for consideration at the hearing by June 2, 2000. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open following the hearing until August 25, 2000. Persons who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (address above) by August 25, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 17, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–10456 Filed 4–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 11, 2000, 8 a.m. to 5:30 p.m. and on May 12, 2000, 8 a.m. to 3 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 11, 2000, the committee will hear updates on activities in the Office of Vaccines Research and Review. The committee will also be informed of issues pertaining to the status of vaccines for the prevention of rotavirus disease. On May 12, 2000, the committee will review issues relating to the development of policy regarding the use of various types of neoplastic cells as substrates for vaccine manufacture.

Procedure: On May 11, 2000, from 9:15 a.m. to 1:45 p.m., and on May 12, 2000, from 9:15 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 4, 2000. Oral presentations from the public will be scheduled between approximately 12:20 p.m. to 12:50 p.m. on May 11, 2000, and between approximately 10:35 a.m. to 10:50 a.m. and between approximately

1:30 p.m. to 1:45 p.m. on May 12, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 4, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On May 11, 2000, from 8 a.m. to 9 a.m., and from approximately 1:45 p.m. to 5:30 p.m., and on May 12, 2000, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information. (5 U.S.C. 552b(c)(4)). These portions will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications.

FDA regrets that it was unable to publish this notice 15 days prior to the May 11 and 12, 2000, Vaccines and Related Biological Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 21, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–10457 Filed 4–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0315]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Collection of Data on Physician Encounters from Medicare+Choice Organizations; *HCFA Form Number:* HCFA–R–0315 (OMB#0938–NEW); *Use* HCFA requires physician encounter data from Medicare+Choice organizations to develop and implement a risk adjustment payment methodology as required by the Balanced Budget Act of 1997; *Frequency:* Monthly; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 300; *Total Annual Responses:* 75.6 million; *Total Annual Hours:* 938,700.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail you request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 17, 2000.

John P. Burke, III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–10478 Filed 4–26–00; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1133–N]

Medicare Program; May 12, 2000, Meeting of the Citizens Advisory Panel on Medicare Education

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Citizens Advisory Panel on Medicare Education (the Panel) on May 12, 2000. This Committee advises and makes recommendations to the Secretary of the Department of Health and Human Services (the Secretary) and the Administrator of the Health Care Financing Administration (HCFA) on opportunities for HCFA to optimize the effectiveness of the National Medicare Education Program and other HCFA programs that help Medicare beneficiaries understand Medicare and the range of Medicare options available with the passage of the Medicare+Choice Program. The Panel meeting is open to the public.

DATES: The meeting is scheduled for May 12, 2000, from 8:00 a.m. until 4:30 p.m.

ADDRESSES: The meeting will be held at the Phoenix Park Hotel, 520 North Capitol Street, NW., Washington, DC 20001, (202) 638–6900.

FOR FURTHER INFORMATION CONTACT: Susana Perry, Executive Director, CBS, Partnership Development Group, Health Care Financing Administration, 7500 Security Boulevard S1–08–07, Baltimore, MD 21244–1850, (410) 786–1076.

Please refer to the HCFA Advisory Committees Information Line (1–877–449–5659 toll free 410–786–9379 local) or the Internet (http://www.hcfa.gov/events/apme/homepage.htm) for additional information and updates on committee activities or by contacting the Executive Director at (http://www.APME@hcfa.gov). Press inquiries are handled through the HCFA Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: The Federal Advisory Committee Act (5 U.S.C. App. 2, Section 10(a)), Public Law 92–463, grants the Secretary the authority to establish an advisory committee if the Secretary finds the committee necessary and in the public interest. The Secretary signed the